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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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03/13/2001

John J. Coogan JR.

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EXAMINER

HANLEY, SUSAN MARIE

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/805,610	<b>Applicant(s)</b> COOGAN ET AL.	
	<b>Examiner</b> Susan Hanley	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-6,8,9,16,17 and 19-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16,17 and 19-21 is/are allowed.
- 6) ☒ Claim(s) 1-6,8 and 9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/9/06 has been entered.

Claims 1-6, 8, 9, 16, 17 and 19-21 are pending.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 8, and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Independent claim 1 has been amended to recite the newly added limitation "in the absence of a sterilizing agent". The support for the amendment is alleged to exist on p. 13 of the specification. The newly added limitation is not fully supported by the disclosure and therefore constitutes NEW MATTER. The specification states that high value/complex fluids are treated to inactivate undesirable pathogens without the addition of chemical additives, photochemical agents and the like, e.g. psoralens, thereby simplifying the treatment and eliminating the need for quenchers and/or post-treatment removal of added materials and/or byproducts (p. 13). The phrase "sterilizing agent" is broad and includes, for example, heat, steam, chlorine gas, UV light, chemical additives, and photochemical agents. The specification provides a

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written description and is enabled only for chemical additives and photochemical agents. Thus, it appears that Applicant was in possession of sterilizing agents limited to chemical additives and photochemical agents. Thus, the new limitation is broad and includes numerous embodiments. The specification is enabling for only two of those embodiments. Therefore, the amendment to claim 1 is deemed to be NEW MATTER.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 8, and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected because the newly added limitation "in the absence of a sterilizing agent" is confusing. Monochromatic UV light is itself a sterilizing agent. Thus, the newly added limitation appears to exclude the previously existing limitation. Blood is a complex fluid that contains riboflavin, an endogenous photosensitizer. It is unclear if blood is excluded from the scope of the claims because it contains an endogenous sterilizing agent.

### *Response to Arguments*

#### *Claim Rejections - 35 USC § 103*

Claims 1, 2, 4-6, and 8 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Holbert et al. (US 5,730,934) or Sizer (US 5,843,374) in view of Morgan et al. (US 5,834,784).

Claims 1-6, 8 and 9 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Stinson (US 5,433,738) in view of Morgan et al. (US 5,834,784).

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Claims 1, 2, 5, 6, 8 and 9 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Stuhl (US 3,986,513) in view of Stinson (US 5,433,738), Hartman (US 6,447,537) and Morgan et al. (US 5,834,784).

Applicant argues that Holbert and Sizer do not teach the sterilization of a fluid. Applicant asserts that Holbert is directed to passing a fluid through a lamp wherein said fluid serves as a cooling function and that Holbert/Sizer teaches sterilization through the photoactivation of hydrogen peroxide. Applicant asserts that Sizer does not teach the a U-shaped tube is utilized to sterilize a complex fluid via exposure to monochromatic light in the absence of a sterilizing agent such that potentially damaging temperature changes to a sensitive components associated with the complex fluid is prevented.

Responding to Applicant's argument that Holbert and Sizer do not teach sterilization and that the fluid passing through the lamp is a coolant, Holbert teaches that the cooling material can be the desired contents for the container (col. 7, lines 5-10 and claims 18-23). Sizer teaches this element at col. 7, lines 47-27. *Holbert teaches that flowing food products comprise juices and milk* (col. 1, lines 15-17). Sizer teaches this element at col. 1, lines 20. *Milk meets the limitation for a complex fluid because it contains heat-sensitive materials (i.e. proteins).* Thus, milk is a complex fluid that contacts a monochromatic light source as it flows into a carton. During this process, *both the milk and the carton are sterilized* because the milk is exposed to the light source. Responding to Applicant's argument that the material is exposed to photoactivated hydrogen peroxide, Holbert teaches that the material *may* be subject to a sterilant prior to irradiation (col. 9, lines 20-24). Responding to Applicant's assertion that the teaching of the U-shaped tube does not teach the sterilization of a complex fluid via exposure to monochromatic light in the absence of a sterilizing agent such that potentially damaging temperature changes to a sensitive components associated with the complex fluid is prevented, the U-shaped tube simply shows the relationship between the cooling fluid flowing on a pathway 38 on the exterior of the lamp and the excimer gas 22. Thus, the cooling fluid, which may be milk, flows through the pathways indicated by Holbert and Sizer and is in thermal contact with a sealed volume that contains the light emitting gas. The excimer gas emits light over the entire

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surface of said cylindrical shell. This disclosure does not teach away from sterilization of a complex fluid via exposure to monochromatic light in the absence of a sterilizing agent such that potentially damaging temperature changes to a sensitive components associated. The disclosure that the lamp is cooled demonstrates that both Sizer and Holbert understood the need to prevent damage to sensitive components in the material.

Applicant argues that Stinson does not teach that a complex fluid is brought into thermal communication with a light emitting surface that is distinct from the complex fluid in order to sterilize a complex fluid via exposure to monochromatic light in the absence of a sterilizing agent such that potentially damaging temperature changes to sensitive components associated with the complex fluid are prevented. Applicant asserts that Stinson is directed to a ventilation fan that would be wholly ineffective to achieve the claimed invention.

Responding to Applicant's argument regarding Stinson's use of a cooling fan, the Examiner stated this deficiency of Stinson and demonstrated that the ordinary artisan would have recognized that the employment of a liquid to cool the lamp is more effect than the use of air for said purpose based on Morgan. The ordinary artisan would have had a reasonable expectation that the apparatus of Morgan et al. could perform the sterilization method of Stinson because it emits the desired wavelength from an excimer gas and has a geometry that is appropriate to accommodate any liquid.

Applicant argues that Stuhl and Hartman are directed to systems that differ in significant respects to the claimed invention which is directed to the sterilization of a complex fluid via exposure to monochromatic light in the absence of a sterilizing agent such that potentially damaging temperature changes to a sensitive components associated with the complex fluid is prevented. Responding to this argument, Applicant has not specifically pointed out the deficiencies in their of these patents. The restatement of the claimed invention does not address the points of the rejection.

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Applicant asserts that it is inappropriate to combine Morgan with any of the cited patents because the lamps employed by Holbert and Sizer were specifically chosen for their ability to excite hydrogen peroxide at 222 nm. Applicant asserts that the skilled artisan would not have been motivated to combine the teaching of Holbert/Sizer with Morgan because of the application of a different wavelength of light for sterilization of a fluid would have resulted in inadequate sterilization of the container surface since the longer wavelength lamps are not efficient for exciting hydrogen peroxide. Applicant also argues that the combination of Holbert/Sizer and Morgan would lead to turbulent flow and risk damage to the instantly complex fluids claimed.

Responding to Applicant's assertion that Holbert and Sizer specifically chose lamps for their ability to excite hydrogen peroxide at 222 nm, both patents teach that a range of excimer gases can be employed and that the use of KrCl to generate a wavelength of 222 nm is one embodiment of their respective inventions (Holbert or Sizer, abstract). Further, Morgan teaches that the excimer gas can be XeBr, but can be changed as desired depending on the wavelength that is needed. Thus, the combination of Holbert/Sizer and Morgan is compatible. Responding to Applicant assertion that the combination of Sizer/Holbert would lead to turbulent flow, Applicant has not presented any evidence/data/reasoning as to why this alleged result would be so.

Applicant argues that there is no motivation to combine Holbert/Sizer and Morgan to arrive at a treatment system for complex fluids, as claimed. Applicant argues that the proposed combination would yield an ineffective and/or inefficient system for sterilization of complex fluids because the systems of Holbert/Sizer rely on a sterilizing agent to achieve the desired effects. Applicant concludes that this would not motivate the ordinary artisan to make the claimed invention. Applicant asserts the proposed combination of Stinson, Stuhl, Hartman and/or Morgan fails to teach or suggest the claimed invention.

Responding to Applicant's assertion that there is no reason to combine Holbert/Sizer and Morgan because Holbert/Sizer rely on a sterilizing agent, as pointed out supra, the use of hydrogen peroxide is one embodiment taught by Holbert/Sizer. It would have been *prima facie* obvious to one of

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ordinary skill in the art at the time the invention was made to substitute the UV light source taught Morgan et al. for the for the light source taught by Sizer et al. or Holbert et al. for the sterilization of complex fluids such as milk by irradiation. The ordinary artisan would have been motivated to do so because both apparatus are *directed to the same purpose*, sterilizing. The sterilization apparatus taught by Morgan et al. is nearly identical to that of Sizer et al. and Holbert et al. The ordinary artisan would have recognized that the separation of the cooling liquid from the complex fluid would be convenient since the cooling liquid could be recirculated and used multiple times without removal from the apparatus. This set up is analogous to a distillation which is a common method for cooling liquids. The ordinary artisan would have had a reasonable expectation that the apparatus of Morgan et al. could perform the sterilization of complex liquids because it emits the desired wavelength from an excimer gas and has a geometry that is appropriate to accommodate any liquid.

Responding to Applicant's assertion that the combination of Stinson, Stuhl, Hartman and/or Morgan fails to teach or suggest the claimed invention, Applicant's argument is not directed to the factual basis of the rejection and is, therefore, non-persuasive.



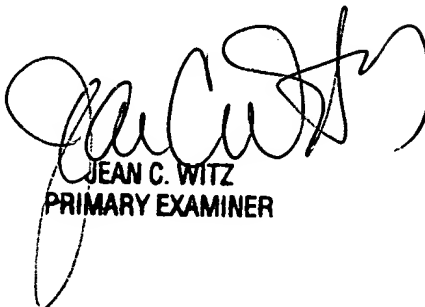
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susan Hanley  
Patent Examiner  
1651



JEAN C. WITZ  
PRIMARY EXAMINER